

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: February 7, 2000  
To: Dockets Management Branch (HFA-305)  
From: Melissa Lamb  
Office of Generic Drugs  
Subject: 180-Day Exclusivity

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This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: 180-Day Exclusivity  
Presented for: FDLI/FDA  
Date Presented: 12/17/99  
Presented by: Douglas L. Sporn  
Number of Pages: 10

M. Lamb

Attachment

90S-0308

M663

**FDLI/FDA**  
**43rd Educational Conference**

**180-Day Exclusivity**

*Douglas L. Sporn, Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration*

**December 17, 1999**

# 180-Day Generic Drug Exclusivity

- August 6, 1999 - Proposed Rule  
Published
- November 4, 1999 - Comment Period  
Closed
- Number of Commentors - 18

## Why a Proposal?

- Previous regulation was successfully challenged in the courts

– *Mova Pharmaceutical Corp v. Shalala, 1998*

– *Granutec, Inc. v. Shalala, 1998*

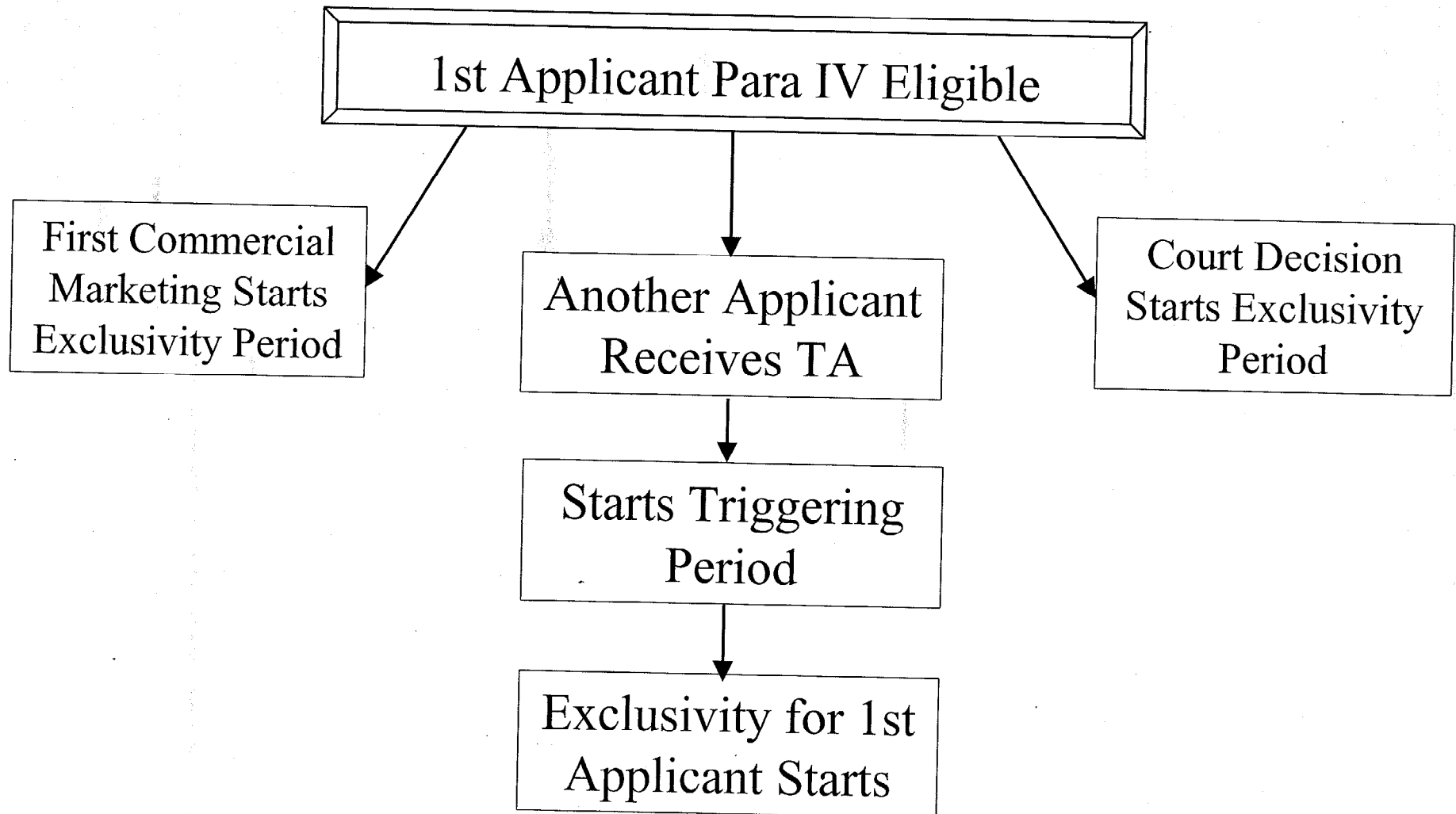
## Who is Eligible?

- Only the First Applicant with Paragraph IV Certification to any Patent
- Substantially Complete Application  
(Including meeting bioequivalence standards for approval)
- Filed

# When Does Exclusivity Begin?

- "A" Court Decision
- First Commercial Marketing
- After the Triggering Period

# What Starts the 180-day Exclusivity Period?



## Triggering Period

- 180 Days - From Tentative Approval of Subsequent Applicant
- 60 Days - First Applicant has Final Approval Not Sued or Case was Settled or Dismissed



# Triggering Period

- Exceptions - Triggering Period Would Not Start Until:
  - 30 Month Stay has Ended
  - Injunction Prohibiting Marketing Expired
  - Statutory Timeframes for RLD  
Exclusivity Expired

# Waivers & Relinquishment

- Applicants May Waive Exclusivity
- Applicants May Relinquish  
Eligibility for Exclusivity

# Multiple Strength/Drug Product Exclusivity

- Each Strength of a Drug Product is Independently Eligible for Exclusivity